

U.S. DISTRICT COURT
FILED AT WHEELING, WV

APR 19 2011

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

NORTHERN DISTRICT OF WV
OFFICE OF THE CLERK

Bayer Schering Pharma AG and
Bayer HealthCare Pharmaceuticals Inc.,

Plaintiffs,

v.

Mylan Pharmaceuticals Inc.,
Mylan Inc., and
Famy Care Ltd.,

Defendants.

Case No. 1:11-cv-53

Jury Trial Demanded

Complaint

Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (collectively "Bayer") bring this Complaint for patent infringement against Defendants Mylan Pharmaceuticals Inc., Mylan Inc., and Famy Care Ltd. (collectively, "Mylan") and allege as follows:

PARTIES

1. Plaintiff Bayer Schering Pharma AG ("Bayer Schering"), formerly known as Schering AG, is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business in Müllerstrasse 178, 13353 Berlin, Germany.

2. Plaintiff Bayer HealthCare Pharmaceuticals Inc. ("Bayer HealthCare"), formerly known as Berlex, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6 West Belt, Wayne, New Jersey 07470.

3. On information and belief, Defendant Mylan Pharmaceuticals Inc. ("MPI") is a corporation organized under the laws of West Virginia, having a principal place of business at

781 Chestnut Ridge Rd., Morgantown, West Virginia 26505.

4. On information and belief, Defendant Mylan Inc. is a corporation organized under the laws of Pennsylvania, having a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Mylan Inc. is registered to do business in the State of West Virginia and has identified Corporation Service Company, 209 West Washington Street, Charleston, WV 25302, as its registered agent for service of process.

5. On information and belief, Defendant Famy Care Ltd. ("Famy Care") is a corporation organized under the laws of India, having a principal place of business at 3rd Floor, Brady House, 12/14, Veer Nariman Road, Fort, Mumbai - 400 001, India.

6. On information and belief, on or about August 6, 2008, Famy Care entered into a partnership with Mylan Inc. pursuant to which the two companies would develop and supply generic oral contraceptives to customers in the United States.

7. On information and belief, Famy Care is in the business of, among other things, manufacturing and marketing generic pharmaceutical products, including oral contraceptives.

8. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products through various operating subsidiaries and partners, including MPI and Famy Care.

9. On information and belief, MPI is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products throughout the United States including within the State of West Virginia.

10. On information and belief, MPI is a wholly-owned subsidiary of Mylan Inc.

11. On information and belief, MPI and Mylan Inc. have common officers and directors.

12. On information and belief, MPI is an alter ego of Mylan Inc.

13. On information and belief, MPI is the U.S. agent for Famy Care with regard to numerous Abbreviated New Drug Application ("ANDAs") held by Famy Care and on file with the U.S. Food and Drug Administration ("FDA"), including without limitation ANDA No. 20-2594.

14. On information and belief, MPI, Mylan Inc., and Famy Care have entered into an agreement whereby MPI will distribute in the United States, including West Virginia, at least the product for which approval is sought by ANDA No. 20-2594, if such ANDA is approved by the FDA.

15. On information and belief, MPI and Mylan Inc. are the alter egos of Famy Care, including without limitation for the purposes of ANDA No. 20-2594.

16. On information and belief and consistent with their stated intentions, following any FDA approval of an ANDA 20-2594, MPI, Mylan Inc., and Famy Care will act in concert to distribute and sell any generic product approved as a result of ANDA 20-2594 throughout the United States, including within West Virginia. On information and belief, MPI, Mylan Inc., and Mylan Pharmaceuticals Inc. know and intend that any generic product approved as a result ANDA No. 20-2594 will be distributed and sold in the United States, including within West Virginia.

17. On information and belief, MPI, Mylan Inc., and Famy Care acted in concert to prepare and submit ANDA No. 20-2594.

18. On information and belief, MPI, Mylan Inc., and Famy Care actively participated in the preparation of ANDA No. 20-2594, and these entities caused submission of this ANDA to the FDA.

JURISDICTION AND VENUE

19. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

20. On information and belief, MPI is subject to personal jurisdiction in the State of West Virginia because, among other things, MPI is a West Virginia corporation with its principal place of business in West Virginia. As such, MPI has purposely availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being haled into court here.

21. MPI has purposely availed itself of the benefits and protections of West Virginia's laws by repeatedly consenting to personal jurisdiction here and/or by bringing suit in this District.

22. On information and belief, by virtue of its incorporation in West Virginia and its maintenance of a principal place of business in West Virginia, MPI has engaged in systematic and continuous business contacts within the State of West Virginia.

23. On information and belief, Mylan Inc. is subject to personal jurisdiction in the State of West Virginia because, among other things, Mylan Inc. (itself and through its wholly-owned operating subsidiary MPI) has purposely availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being haled into court here.

24. Mylan Inc. has purposely availed itself of the benefits and protections of West Virginia's laws by registering with the State of West Virginia to do business in West Virginia and by maintaining an agent for service of process in West Virginia. By maintaining an agent

for service of process in West Virginia, MPI has reasonably anticipated being haled into court here.

25. Mylan Inc. has purposely availed itself of the benefits and protections of West Virginia's laws by repeatedly consenting to personal jurisdiction here and/or by bringing suit in this District.

26. On information and belief, Mylan Inc. (itself and through its wholly-owned operating subsidiary MPI) markets and sells generic drugs throughout the United States and in particular within the State of West Virginia and maintains administrative offices in the State of West Virginia, and therefore Mylan Inc. transacts business within the State of West Virginia such that it has engaged in systematic and continuous business contacts within the State of West Virginia. In addition, Mylan Inc. is subject to personal jurisdiction in West Virginia because, on information and belief, it controls and dominates MPI and therefore the activities of MPI in this jurisdiction are attributed to Mylan Inc.

27. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) markets its generic drug products to residents of the State of West Virginia through its website.

28. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) offers its generic drug products for sale to residents of the State of West Virginia on third-party websites that West Virginia residents can use to purchase Mylan Inc.'s products for shipment to and within the State of West Virginia.

29. On information and belief, residents of the State of West Virginia purchase generic drug products from Mylan Inc. (itself or through its subsidiary MPI) in the State of West Virginia.

30. On information and belief, Mylan Inc. (itself or through its subsidiary MPI)

receives revenue from the sales and marketing of its generic drug products in the State of West Virginia.

31. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) uses sales representatives in the State of West Virginia to promote the sales of Mylan Inc.'s generic drugs throughout the State of West Virginia.

32. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) has attended trade shows in the State of West Virginia for the purpose of promoting and selling Mylan Inc.'s generic drug products.

33. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) has several authorized distributors in the State of West Virginia to distribute Mylan Inc.'s generic drug products throughout the State of West Virginia.

34. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) plans to market and sell the product that is the subject of ANDA No. 20-2594, if approved, in the State of West Virginia as an alternative to Bayer's YAZ® product currently being sold in the State of West Virginia.

35. On information and belief, Famy Care is subject to personal jurisdiction in the State of West Virginia because, among other things, Famy Care, itself and through its agent MPI and its partner Mylan Inc., has purposely availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being haled into court here.

36. Famy Care has purposely availed itself of the benefits and protections of West Virginia's laws by designating MPI as its U.S. agent for numerous ANDA applications (including ANDA 20-3594). MPI is a West Virginia corporation with its principle place of business in West Virginia. By designating a West Virginia corporation with continuous and

systematic contacts in West Virginia as its agent, Famy Care has reasonably anticipated being haled into court here.

37. Famy Care has purposely availed itself of the benefits and protections of West Virginia's laws by entering into a partnership with Mylan Inc. to develop and supply generic oral contraceptives in the United States and in the State of West Virginia. Mylan Inc. has registered with the State of West Virginia to do business in West Virginia and maintains an agent for service of process in West Virginia. By entering into a partnership with a party that maintains an agent for service of process in West Virginia, Famy Care has reasonably anticipated being haled into court here.

38. On information and belief, Famy Care, itself and through its agent MPI and its partner Mylan Inc., markets and sells generic drugs throughout the United States and in particular within the State of West Virginia, and therefore Famy Care transacts business within the State of West Virginia such that it has engaged in systematic and continuous business contacts within the State of West Virginia.

39. On information and belief, Famy Care (itself or through its agent MPI and its partner Mylan Inc.) markets its generic drug products to residents of the State of West Virginia through its website.

40. On information and belief, Famy Care (itself or through its agent MPI and its partner Mylan Inc.) offers its generic drug products for sale to residents of the State of West Virginia on third-party websites that West Virginia residents can use to purchase Famy Care's products for shipment to and within the State of West Virginia.

41. On information and belief, residents of the State of West Virginia purchase generic drug products from Famy Care (itself or through its agent MPI and its partner Mylan

Inc.) in the State of West Virginia.

42. On information and belief, Famy Care (itself or through its agent MPI and its partner Mylan Inc.) receives revenue from the sales and marketing of its generic drug products in the State of West Virginia.

43. On information and belief, Famy Care (itself or through its agent MPI and its partner Mylan Inc.) uses sales representatives in the State of West Virginia to promote the sales of Famy Care's generic drugs throughout the State of West Virginia.

44. On information and belief, Famy Care (itself or through its agent MPI and its partner Mylan Inc.) has attended trade shows in the State of West Virginia for the purpose of promoting and selling Famy Care's generic drug products.

45. On information and belief, Famy Care (itself or through its agent MPI and its partner Mylan Inc.) has several authorized distributors in the State of West Virginia to distribute Famy Care's generic drug products throughout the State of West Virginia.

46. On information and belief, Famy Care (itself or through its agent MPI and its partner Mylan Inc.) plans to market and sell the product that is the subject of ANDA No. 20-2594, if approved, in the State of West Virginia as an alternative to Bayer's YAZ® product currently being sold in the State of West Virginia.

47. Venue is proper under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

BACKGROUND

48. Bayer HealthCare is the holder of approved New Drug Application ("NDA") No. 21-676 for YAZ® tablets, which contain as active ingredients micronized drospirenone and micronized 17 α -ethinylestradiol. The United States Food and Drug Administration ("FDA") has

approved YAZ® tablets for the prevention of pregnancy in women and for the treatment of moderate acne and the symptoms of premenstrual dysphoric disorder in women who elect to use an oral contraceptive.

49. Bayer HealthCare sells YAZ® tablets in the United States as a 28-day oral contraceptive regimen that contains 24 tablets comprising 3 mg of micronized drospirenone and 0.02 mg of micronized 17 α -ethinylestradiol plus 4 placebo tablets.

50. On information and belief, Mylan submitted to the FDA ANDA No. 20-2594 (“Mylan’s ANDA”) under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of a generic version of Bayer’s YAZ® tablets.

51. On information and belief, the composition of the product that is the subject of Mylan’s ANDA contains 3 mg of drospirenone and 0.02 mg of ethinylestradiol in tablet form for oral contraception in a human female (hereinafter “Mylan’s YAZ® ANDA product”).

52. On information and belief, Mylan’s ANDA seeks approval of a 28-day oral contraceptive regimen that contains 24 tablets comprising 3 mg of drospirenone and 0.02 mg 17 α -ethinylestradiol plus 4 placebo tablets.

53. On information and belief, on or about March 7, 2011, Mylan sent a Notice Letter to Plaintiffs Bayer Schering and Bayer HealthCare, purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto.

PATENT-IN-SUIT

54. The patent-in-suit is United States Reissue Patent No. 37,564 (“the ’564 reissue patent”).

55. The '564 reissue patent issued on February 26, 2002. Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their application for this patent on February 15, 2000. Bayer Schering is the current owner of the '564 reissue patent. Bayer attaches a true and correct copy of the '564 reissue patent as Exhibit 1.

COUNT ONE: CLAIM FOR PATENT INFRINGEMENT OF THE '564 REISSUE PATENT

56. Bayer incorporates paragraphs 1-55 of this Complaint as if fully set forth herein.

57. On information and belief, Mylan's YAZ® ANDA product infringes one or more claims of the '564 reissue patent.

58. The '564 reissue patent covers Bayer HealthCare's YAZ® tablets, and Bayer has listed the '564 reissue patent for YAZ® in the FDA *Approved Drug Products and Therapeutic Equivalence Evaluations* ("the Orange Book").

59. On information and belief, Mylan submitted ANDA No. 20-2594 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's YAZ® ANDA product before the expiration of the '564 reissue patent.

60. On information and belief, Mylan made and included in ANDA No. 20-2594 a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '564 reissue patent is invalid or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of Mylan's YAZ® ANDA product.

61. By filing ANDA No. 20-2594 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's YAZ® ANDA product before the expiration of the '564 reissue patent,

Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's YAZ® ANDA product will also infringe one or more claims of the '564 reissue patent.

62. Plaintiffs Bayer Schering and Bayer HealthCare are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to ANDA No. 20-2594 shall be a date which is not earlier than June 30, 2014, the current expiration date of the '564 reissue patent, or any later date of exclusivity to which Bayer becomes entitled. Bayer Schering and Bayer HealthCare are entitled to an award of damages and treble damages for any commercial sale or use of Mylan's YAZ® ANDA product, and any act committed by Mylan with respect to the subject matter claimed in the '564 reissue patent that is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

63. On information and belief, when Mylan filed ANDA No. 20-2594, it was aware of the '564 reissue patent and was aware that the filing of ANDA No. 20-2594 with the request for its approval prior to the expiration of the '564 reissue patent constituted an act of infringement of the '564 reissue patent.

PRAYER FOR RELIEF

WHEREFORE Bayer respectfully requests the following relief:

A. Judgment that Mylan has infringed one or more claims of the '564 reissue patent by filing ANDA No. 20-2594 relating to Mylan's YAZ® ANDA product containing drospirenone and ethinylestradiol;

B. A permanent injunction restraining and enjoining Mylan and its officers, agents,

attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States or its territories, or importation into the United States or its territories, of Mylan's YAZ® ANDA product;

C. An order that the effective date of any approval of Mylan's ANDA No. 20-2594 relating to Mylan's YAZ® ANDA product containing drospirenone and ethinylestradiol be a date which is not earlier than June 30, 2014, the expiration date of the '564 reissue patent, or any later date of exclusivity to which Bayer becomes entitled;


D. Damages and treble damages from Mylan for any commercial activity constituting infringement of the '564 reissue patent; and

E. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Bayer hereby demands a jury trial on all issues so triable.

Dated: April 19, 2011


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